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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,298	07/02/2001	Steven M. Ruben	PZ035P1C1	4425

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EXAMINER
O HARA, EILEEN B

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1646	4

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/895,298	Applicant(s) RUBEN ET AL.	
	Examiner Eileen B. O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-24 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-XLVII. Claims 1-10, 14, 15 and 21, drawn to polynucleotide, vector, host cells, and method of recombinantly producing protein, of genes 1-47 of Table 1, respectively, classified in class 536, subclass 23.5, class 435, subclasses 320.1 and 252.3. (For example, Invention I is gene 1, Invention II is gene 2, etc.)

XLVIII-XCIV. Claims 11-12 and 16, drawn to polypeptide encoded by the polynucleotide of genes 1-47 of Table 1, respectively, classified in class 530, subclass 350.

XCV-CXLI. Claim 13, drawn to antibody that binds specifically to the polypeptide encoded by the polynucleotide of genes 1-47 of Table 1, respectively, classified in class 530, subclass 388.22, for example.

CXLII-CLXXXVIII. Claim 17, in so far as it is drawn to a method of treatment by administering a polypeptide encoded by the polynucleotide of genes 1-47 of Table 1, respectively, classified in class 514, subclass 2.

CLXXXIX-CCXXXV. Claim 24, in so far as it is drawn to a method of treatment by administering a polynucleotide of one of genes 1-47 of Table 1, respectively, classified in class 514, subclass 2.

CCXXXVI-CCLXXXII. Claim 18, drawn to a method of diagnosing a pathological condition or susceptibility to a pathological condition by detecting a mutation in the polynucleotide of genes 1-47 of Table 1, respectively, classified in class 436, subclass 6, for example.

CCLXXXIII-CCCXXIX. Claims 19 and 20, drawn to a method of diagnosing a pathological condition or susceptibility to a pathological condition by determining the presence or amount of expression a polypeptide or a method for identifying a binding partner to a polypeptide encoded by the polynucleotide of genes 1-47 of Table 1, respectively, classified in class 436, subclass 501, for example.

CCCXXX-CCCLXXVI. Claim 22, drawn to a method of identifying an activity in a biological assay by expressing a polynucleotide of genes 1-47 of Table 1, respectively, in a cell, isolating the supernatant, detecting activity in a biological assay, and identifying the protein in the supernatant having the activity, classified in class 435, subclass 4.

CCCLXXVII-CDXXIII. Claim 23, drawn to a product of unspecified constitution that is identified as a binding partner to a polypeptide encoded by the polynucleotide of genes 1-47 of Table 1, respectively, class and subclass not determinable.

3. The inventions are distinct, each from the other because of the following reasons:

In order to facilitate the restriction requirement, the 47 distinct nucleotide/protein/antibody/method groups are grouped together. However, each member of each group is a distinct invention because the nucleic acids that are Inventions I-XLVII are

unrelated to each other because the polynucleotides that have different nucleotide sequences, are located at different loci on different chromosomes, are expressed in different tissues, and encode proteins that are homologous to different proteins. Therefore, the proteins encoded by the polynucleotides, the antibodies to the different proteins, and the methods of using the polynucleotides, proteins and antibodies each constitute distinct inventions.

The nucleic acids that are Inventions I-XLVII are related to the proteins of Inventions XLVIII-XCIV by virtue of encoding the same. The polypeptides have utility for the recombinant production of protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of the proteins, such as nucleic acid hybridization assays.

The proteins that are Inventions XLVIII-XCIV are related to the antibodies of Inventions XCV-CXLI by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural protein.

The polynucleotides that are Inventions I-XLVII are related to the antibodies of Inventions XCV-CXLI by virtue of encoding the polypeptide, which is the cognate antigen,

necessary for the production of the antibodies, but the polynucleotides and antibodies are independent and distinct inventions because they are structurally and functionally different chemical compounds, each of which can be used without the other.

Inventions XLVIII-XCIV, CCLXXXIII-CCCXXIX and CCCLXXVII-CDXXIII are related as process of identifying and product identified. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of unspecified composition that is identified as binding to the polypeptide is a distinct chemical compound that can be made and used without the polypeptide. The polypeptide can be used in another method, such as a method of treatment, which is a materially different method, and the method of identifying can be used to identify another compound that binds to the polypeptide.

The polynucleotides that are Inventions I-XLVII are related to the product of unknown composition of Inventions CCCLXXVII-CDXXIII by virtue of encoding the polypeptide, which is used in the method of identifying the product, but the polynucleotides are independent and distinct inventions because they are structurally and functionally different chemical compounds from the product, and can be made and used without the other.

Inventions XCV-CXLI and Inventions CCCLXXVII-CDXXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies are structurally and functionally different chemical compounds from the product, and each can be made and used without the other.

Inventions I-XLVII and each of Inventions CLXXXIX-CCXXXV , CCXXXVI-CCLXXXII, CCLXXXIII-CCCXXIX and CCCXXX-CCCLXXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in the method of treatment, or in a method of diagnosing a pathological disease, or in a method of identifying a compound that binds to a polypeptide (by expressing the nucleic acid in a cell to produce the polypeptide used in the assay), or in a method of identifying an activity in an assay by expressing the polynucleotide, detecting activity and identifying a protein, all of which are materially different methods that have different method steps and goals.

The polynucleotides that are Inventions I-XLVII are related to the method of treatment with the polypeptide that are Inventions CXLII-CLXXXVIII by virtue of the polynucleotides encoding the polypeptide, but the polynucleotides can also be used in a method of treatment or of diagnosis, which are materially different methods.

Inventions XCV-CXLI and CCLXXXIII-CCCXXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a method of diagnosis by determining the presence or amount of a polypeptide in a subject, but the

antibodies can also be used in a method of purifying a protein or in a method of treatment, which are materially different methods.

Inventions XLVIII-XCIV is related to each of Inventions CXLII-CLXXXVIII and CCLXXXIII-CCCXXIX related as product and process of use. The polypeptides can be used in a method of treatment or in a method of identifying a compound that binds to it, each of which are materially different methods that have different method steps and goals.

Inventions XCV-CXLI and each of Inventions CXLII-CLXXXVII, CLXXXIX-CCXXXV, CCXXXVI-CCLXXXII and CCCXXX-CCCLXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies are not used or defined in the methods.

Inventions XLVIII-XCIV and each of Inventions CLXXXIX-CCXXXV, CCXXXVI-CCLXXXII and CCCXXX-CCCLXXVI are unrelated. The polypeptides are not used or defined in the methods of treatment with a polynucleotide, or diagnosing a disease by identifying a mutation in a polynucleotide, or in a method of identifying an activity in a biological assay by expressing a polynucleotide.

Inventions CCCLXXVII-CDXXIII and each of Inventions CXLII-CLXXXVIII, CLXXXIX-CCXXXV, CCXXXVI-CCLXXXII and CCCXXX-CCCLXXVI are unrelated. The product of unspecified composition is not used or defined in the methods of treatment with a polypeptide, or in the methods of treatment with a polynucleotide, or diagnosing a disease by identifying a mutation in a polynucleotide, or in a method of identifying an activity in a biological assay by expressing a polynucleotide.

The methods of Inventions CXLII-CLXXXVIII, CLXXXIX-CCXXXV, CCXXXVI-CCLXXXII, CCLXXXIII-CCCXXIX and CCCXXX-CCCLXXVI are all unrelated to each other. The methods of the different inventions require different starting compounds and have different steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the need for non-coextensive literature search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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